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| APPLICATION NO.                  | FI    | LING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------|------------|----------------------|---------------------|------------------|
| 10/622,502 07/1                  |       | 7/18/2003  | Uwe Marx             | Weh212T1            | 3800             |
| ;                                | 590   | 10/25/2005 |                      | EXAMINER            |                  |
| Horst Kasper                     |       |            | AFREMOVA, VERA       |                     |                  |
| 13 Forest Drive Warren, NJ 07059 |       |            |                      | ART UNIT            | PAPER NUMBER     |
| warren, NJ                       | 11039 |            |                      | 1651                | <u> </u>         |

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)   |  |  |  |
|--|--|--|--|--|--|
| Office Action Commence   | 10/622,502   | MARX ET AL.  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit   |  |  |  |
|  | Vera Afremova  | 1651   |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c   | orrespondence address  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).   | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status ·   |  |  |  |  |  |
| Responsive to communication(s) filed on 7/19/3  2a) This action is FINAL. 2b) This  3) Since this application is in condition for allowant closed in accordance with the practice under E  | action is non-final.  ace except for formal matters, pro   |  |  |  |  |
| Disposition of Claims  |  |  |  |  |  |
| 4)  Claim(s) 1-23 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5)  Claim(s) is/are allowed. 6)  Claim(s) is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) 1-23 are subject to restriction and/or e   |  |  |  |  |  |
| Application Papers   |  |  |  |  |  |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the original than the correction of the correction of the original than the correction of the correcti | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj  | e 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).                        |  |  |  |
| Priority under 35 U.S.C. § 119   |  | •  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |  |  |  |  |
| Attachment(s)  |  | ·  |  |  |  |
| Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa  |  |  |  |  |

## **DETAILED ACTION**

Claims 1-23 are pending and subject to restriction requirement.

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a method for cultivation cells at high densities, classified in class 435, subclass 243, for example.
- II. Claims 11-18 and 23, drawn to an apparatus for cultivation cells at high densities comprising cultivation chamber(s) with semipermeable separation from supply container(s) and product collection container(s), classified in class 435, subclass 283.1+, for example.
- III. Claims 19-22, drawn to a method for generating products by culturing cells at high densities in an apparatus for cultivation cells at high densities, classified in class 435, subclass 41+, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III and Invention II are related as processes and apparatus for their practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, cells can be cultured at high densities in confluent monolayer on and/or an apparatus comprising cultivation chamber(s) with semipermeable separation from supply container(s) and product collection container(s) can be used for culturing cells at low densities and generating products from cells at low densities.

Inventions I and III are distinct because the claimed methods appear to encompass making distinct products such as cell mass of high density (group I) and various cellular product(s) separated from the cell mass of high density as presently claimed. Moreover, claims 19-21, in particular, provides for the use of apparatus, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one group is not necessarily required for the other groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1651

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

October 24, 2005

VERA AFREMOVA

V. Hhr

PRIMARY EXAMINER